DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M2759n

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

July 12, 1999

WARNING LETTER

Certified Mail
Return Receipt Requested

John D. Moyer, President
Moyer & Son Inc.
113 East Reliance Road
Souderton, PA 18964

Dear Mr. Moyer:

On May 4, 1999 Food and Drug Administration (FDA) Investigator Debra Bennett and Pennsylvania Department of Agriculture (PDA) Investigators Steven T. Detwiler and Howard Walker conducted an inspection of your firm Moyer & Son Inc., located in Souderton, PA, regarding the manufacture of medicated feeds. The inspection revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not confirm to, or are not operated in conformity with Title 21, Code of Federal Regulations, Part 225. At the conclusion of the inspection, a Form FDA 483, list of inspectional observations was issued to and discussed with Mr. Stephen Wasser, Mill Supervisor (copy enclosed). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection found the following deviations:

Clean-out procedures are not adequate for all equipment used in the manufacture of medicated feeds to assure that medicated feeds are not contaminated with other drugs. For example, the mixer that utilizes molasses had a build-up of feed material in the area where drugs are added.

Failure to investigate an out of tolerance assay for a medicated chicken feed, batch [redacted], containing [redacted]. The analysis found [redacted] of declared); the expected level was [redacted].

There is no assurance that proper manufacturing codes (lot numbers) are recorded on the production records.

Distribution records for medicated feeds do not contain lot numbers.

Our inspection also found that production overages were not explained in the production records, and medicated feed proofread labels were not maintained for one year after all labels from that batch was used.

The above is not intended to be an all-inclusive list of deficiencies which exist at your firm. As a manufacturer of medicated feeds, you are responsible for assuring that your overall operation and products you manufacture and distribute are in compliance with all the requirements of the Food, Drug, and Cosmetic Act.

You should take prompt action to correct the above deficiencies and to establish procedures whereby they will not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the reoccurrence of similar violations. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the attention of James C. Illuminati, Compliance Officer, at the address referenced above.

Sincerely,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District

jci

cc: PENNSYLVANIA STATE DEPARTMENT OF AGRICULTURE
Bureau of Plant Industry
2301 North Cameron Street
Harrisburg, PA 17110-9408
Attn: Earl M. Haas
Feed Program Specialist

PENNSYLVANIA STATE DEPARTMENT OF AGRICULTURE
Bureau of Animal Health and Diagnostic Services (BAHDS)
2301 North Cameron Street
Harrisburg, PA 17120
Attn: Dr. John I. Enck
Director